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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,792	01/04/2002	Anthony Krantis	ENP-001.1P US	7680

7590 01/12/2006
Leon R Yankwich
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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,792	Applicant(s) KRANTIS ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02032003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the articles missing from the information disclosure statement. A new signed copy is enclosed which indicates these references have been considered. However, as applicant has indicated that some entry designations were made in error, a corrected PYOL-1449 should be filed by applicant so that the correct entries may be indicated for consideration in the file.

Receipt is also acknowledged of the amendment and extension of time filed 09/25/2005. However, a new set of claims was filed on 10/19/2005. The set filed 09/25/2005 appears to be filed in response to the previous election/restriction requirement. The filing of 10/19/2005 appears to be in response to the prior office action mailed 04/19/2005. The mailing of 09/25/2005 also seems to be a duplicate of the preliminary amendment which was filed 08/14/2003.

The rejection under 35 USC 112, (first and second paragraph regarding "non toxic")

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bergsjö et al (AG), further in view of Williams (DR).

Bergsjö shows that feeding pigs DON decreases body weight gain (see Abstract; page 293, last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The Fusarium mycotoxin is listed and is inclusive of Don (see Bergsjö et al). As such the instant method is clearly anticipated by Bergsjö et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Bergsjö in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of tricothecenes such as DON would therefore be obvious in view of the teaching of Bergsjö in view of Williams.

Claims 1-7 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arnold et al (AC) in view of Williams (DR).

Arnold et al disclose that exposure to DON causes a reduction in body weight (see Abstract; page 695, second to last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The Fusarium mycotoxin is listed and is inclusive of Don (see Arnold et al). As such the instant method is clearly anticipated by Arnold et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Arnold et al in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of tricothecenes such as DON would therefore be obvious in view of the teaching of Arnold in view of Williams.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friend et al (BK) in view of Williams (DR).

Friend et al disclose that exposure to DON (vomitoxin) reduces weight gain in pigs (See page 773, last paragraph). This is equivalent to a treatment of obesity. Further, the effects of T-2 mycotoxins such as trichothecene is well known as an inherent property of that molecule. If the alternative, this property of tricothecenes on gastric motility is disclosed by Williams et al at page 374. Williams also draws an equivalence between clinical symptoms in humans, cattle, swine and bird. The Fusarium mycotoxin is listed and is inclusive of Don (see Friend et al). As such the instant method is clearly anticipated by Friend et al et al if the effects of gastric motility are viewed as an inherent property of that molecule. If in the alternative, it is not viewed as inherent, those of ordinary skill would expect similar decreases in weight as well as gastric motility effects in humans, cattle, pigs or birds given the disclosure of Friend et al in view of Williams. The treatment of obesity and effects on gastric motility produced by administration of trichothecenes such as DON would therefore be obvious in view of the teaching of Friend et al in view of Williams.

Response to Arguments

Applicant's arguments filed 10/19/2005 have been fully considered but they are not persuasive.

Regarding the rejection under 35 USC 102(b) over Bergsjö et al in view of Williams et al, applicant argues that like all the prior art, Bergsjö et al merely disclose

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the toxic effects of the claimed trichothecene related compounds. As a result, applicant argues that the prior art does not disclose the therapeutically effective amount and/or therapeutic effect of the claimed compounds. In response, it must be pointed out, that applicant describes the “pharmaceutical effect” of these compounds (page 31 of the specification, line 31). Further, the claims merely set out an “effective amount”, so that the weight loss effect described by Bergsjö et al is sufficient to satisfy this limitation.

Further, as pointed out in the rejection, Bergsjö et al show that animals who consumed these compounds suffered from weight loss. This is inherently a weight loss or method of treating obesity, given that the same compounds are administered in the same way. Since applicant is administering the same compounds for the same or equivalent purpose of weight loss (whether for therapeutic purposes or not), the disclosure of Bergsjö et al is viewed as anticipating the instant claims. The mechanism by which this is accomplished (increased gastric motility) is viewed as a heretofore undiscovered inherent action of these compounds. If however one views Bergsjö et al as rendering the instant method obvious, the Williams reference is merely used to show equivalent action in cattle and humans, as well as demonstrating the compounds effects on gastric motility. Again, while Williams describes the toxic effects of these compounds, it is recognized that the “effective amount” as described by Williams is sufficient to produce weight loss, and further is associated with changes in gastric motility.

Applicant further argues that the crops fed to animals by Bergsjö et al are contaminated by trichothene related compounds and it is unclear what role these compounds play in the regulation of weight in the test animals. It is noted however Applicant's claim language does not exclude these compounds by using the open ended "comprising" in setting out the claimed invention.

Similarly, in the rejection based on Arnold et al in view of Williams et al, Arnold et al again recognizes the effect of weight loss on animals feeding on crops containing these compounds. The Fusarium mycotoxin is inclusive of the DON compound as instantly claimed. Weight loss and treatment of obesity are recognized equivalents, and since applicant is setting out the "effective amount" (the specification supports "pharmaceutically effective amount"), the Arnold reference shows that the pharmaceutically effective amount provided produces the desired weight loss claimed by applicants. If the effect of these compounds on gastric motility across species is viewed as inherent, Arnold et al (like Bergsjö et al above) would be viewed as anticipatory. If however, it is viewed as reference under 35 USC 103(a), the reference by Williams et al provides the teaching that the effect on gastric motility is well known across species.

As above, the contamination of the crops by related compounds is not excluded by applicant's use of open-ended language (comprising).

Similarly, Friend discloses the weight loss caused by contamination of crops by Don et al. As above, this satisfies applicant's use the terms "effective amount". Applicant further questions the role of other compounds in Friends experiment, but fails to note the use of "comprising" language in the instant claims which would not exclude such compounds from being present.

At the core of all these arguments is the distinction from applicant's claimed **treatment** of obesity and the weight loss observed in the references cited. While the prior art does approach these compounds for their toxic effects, such effects fall within the definition of "pharmaceutically effective amount" set out by applicants in the specification. What is viewed as a beneficial effect in obese animals and humans, is viewed as an undesired effect in healthy animals and humans. This distinction comes from the patient population, not from what is inherent to the action of the claimed compounds. Certainly, the same undesired weight loss effects found in healthy animals would occur in humans who consumed these compounds. However, in those suffering from obesity, the only difference is in the final effect the compounds have on the weight of the cattle or human. In either case, the compounds being used are known toxins. Their pharmaceutical effect is therefore the same in either obese or normal patients or cattle. The method of effecting that change is identical and is art recognized. For these reasons, the rejections cited above are maintained in this action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claims 8-39 drawn to an invention nonelected with traverse in Paper No. 02032004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

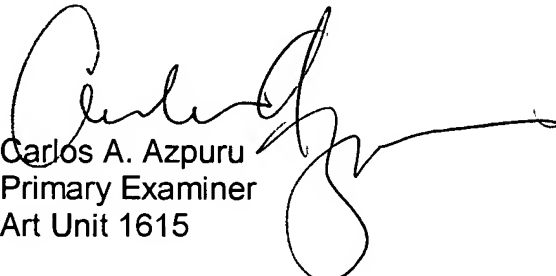
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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